K070446

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SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Cool-tip™ Switching Controller

1. Submitter Information

Valleylab
A division of Tyco Healthcare Group LP
5920 Longbow Drive
Boulder, CO 80301
Contact: Julie Ross
Senior Regulatory Associate
Telephone: 303-581-6773

MAY - 2 2007

Date summary prepared: February 14, 2007

2. Name of Device

Trade or Proprietary Name: Cool-tip™ Switching Controller

Common/Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories

3. Predicate Devices

The intended use of the Cool-tip™ Switching Controller is identical to that of the Cool-tip™ RF System. The Cool-tip™ RF System received initial FDA clearance in 510(k)s K973297 (10/29/97) and K984552 (3/5/99). Additional clearance with the Cool-tip™ RF System was obtained for specific claims under 510(k)s K042216 (Liver lesions, 11/12/04), K052796 (Osteoid Osteoma claim, 2/3/06) and K053290 (Liver tumor claim, 3/15/06).

4. Device Description

The Cool-tip™ Switching Controller (CTSW Control) is an adjunct device for the Cool-tip™ RF Ablation Generator. Power from the generator is routed to the controller and allows the physician to ablate lesions with one single Cool-tip electrode or one cluster electrode, or simultaneously with two or three single pre-placed electrodes. The controller sequentially switches power between the electrodes. Power is applied to the first electrode until the tissue impedance rises to the target value (30 percent above the baseline value), or until 30 seconds have elapsed. Then power is switched to the next electrode. Power is switched repeatedly until the selected procedure time is reached.

The controller does not alter the basic functions available on the generator. The controller has the same timing, temperature measurement, and impedance measurement functions available on the generator. The controller does not change the power available at the electrodes compared to the generator without the controller. The indications for use and the control mechanisms for the Switching Controller remain the same as for the generator.

The Switching Controller is an accessory that allows for the simultaneous activation of multiple electrodes. Activation of multiple electrodes during a single treatment session is a convenience for the physician and allows for the ablation of multiple lesions simultaneously, or for the ablation of one large tumor when the electrodes are placed 2 cm apart. Placing three single electrodes in close proximity produces a cluster electrode where the physician is controlling the cluster spacing. The controller automates the manual function of cauterization of the electrode track by controlling the temperature during electrode removal.

The front panel of the Switching Controller contains an on/off power switch, activation switches for ablation and cauterization, ablation timer displaysand buttons, three (3) electrode ports for the connection of selected electrodes, three (3) buttons for activating selected electrode channels, three (3) temperature probe displays with adjacent green bars to indicate the activated electrode channel, and three (3) current/watts displays for each electrode channel.

The Cool-tip™ Switching Controller is comprised of the following components:

- Switching controller
- Cable, which delivers power from the generator to the controller

The Switching Controller is connected to the Cool-tip RF generator by a dedicated cable that delivers power from the generator to the switching controller. The Switching Controller cannot direct power to the electrodes without the generator.

5. Intended Use

The intended use of the Cool-tip™ Switching Controller is identical to that of the Cool-tip™ RF System, as follows:

"The Cool-tip™ Switching Controller is to be used with the Cool-tip™ RF System and is intended for use in percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue, such as the partial or complete ablation of non-resectable liver tumors, and osteoid osteoma tumors within bone."

6. Summary of Technological Characteristics

The Cool-tip™ Switching Controller (CTSW Control) is an adjunct device for the Cool-tip™ RF Ablation Generator. The Switching Controller is an accessory that allows for the simultaneous activation of multiple pre-placed electrodes. The Cool-tip™ Switching Controller has the same basic technological characteristics as the predicate device noted above.

7. Performance and Clinical Data

Radiofrequency ablation with the Cool-tip™ Switching Controller has proven to be safe and efficacious for the ablation of tissue. Preclinical testing on bovine liver (*ex vivo* and *in vivo*) verified that the lesions produced using the Cool-tip™ Switching Controller and Cool-tip™ Generator, along with various electrode configurations, are comparable to those lesions produced by the Cool-tip Generator only and with the same electrode configurations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2007

Valleylab
% Ms. Julie Ross
Senior Regulatory Associate
5920 Longbow Drive
Boulder, Colorado 80301-3299

Re: K070446
Trade/Device Name: Cool-tip™ Switching Controller
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 14, 2007
Received: February 15, 2007

Dear Ms. Ross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070446

Device Name: _____ Cool-tip™ Switching Controller _____

Indications for Use:

"The Cool-tip™ RF Switching Controller is to be used with the Cool-tip™ RF System and is intended for use in percutaneous, laparoscopic, intraoperative coagulation and ablation of tissue, such as the partial or complete ablation of non-resectable liver tumors, and osteoid osteoma tumors within bone."

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070446